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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,661	01/23/2001	J. Richard Sportsman	LJL 35101	3789

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EXAMINER
NICHOLS, CHRISTOPHER J

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 08/26/2002 4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/768,661	SPORTSMAN ET AL.	
	Examiner	Art Unit	
	Christopher Nichols, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12 and 16 drawn to a method for detecting activation of a receptor with, classification dependent upon how light is measured.

II. Claims 13-14 drawn to a nonpeptide luminescently labeled tracer comprising a luminophore coupled to a nonhydrolyzable guanosine triphosphate (GTPγ-S), classified in class 536, subclass 26.6, for example.

III. Claim 15 drawn to measuring the concentration of the activated form of a 7-transmembrane-spanning domain receptor, classification dependent on how light is measured.

IV. Claims 17-21 drawn to a nonpeptide luminescently labeled tracer comprising a luminophore coupled to a cyclic nucleotide, classified in class 536, subclass 26.6, for example.

V. Claims 22-28 drawn to determining the concentration of a cyclic nucleotide, classification dependent on how light is measured.

VI. Claims 29-30 drawn to a method of identifying a compound as a modulator of a receptor or enzyme that generates a cyclic nucleotide, classification dependent upon how light is measured.

VII. Claims 31-34 drawn to a kit, classification dependent upon components.

VIII. Claim 35 drawn to a lysis buffer and kits comprising same, classification dependent on buffer composition.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I, III, V, and VI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of detecting activation of a receptor, which is not required by any of the other Inventions. Invention III requires search and consideration of measuring the concentration of the activated form of a 7-transmembrane-spanning domain receptor, which is not required by any of the other Inventions. Invention V requires search and consideration of determining the concentration of a cyclic nucleotide, which is not required by any of the other Inventions. Invention VI requires search and consideration of a method of identifying a compound as a modulator of a receptor or enzyme, which is not required by any of the other Inventions. Therefore, a search and examination of all of the methods in one patent application would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions II, IV, VII, and VIII are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably

distinct. The nonpeptide luminescently labeled tracer comprising a luminophore coupled to a nonhydrolyzable guanosine triphosphate (GTPγ-S) of Invention II is independent and distinct from the products of Inventions IV, VII, and VIII, because none are required to make or use the nonpeptide luminescently labeled tracer comprising a luminophore coupled to a nonhydrolyzable guanosine triphosphate (GTPγ-S) of Invention II. The nonpeptide luminophore coupled to cyclic nucleotide of Invention IV is independent and distinct from the products of Inventions II, VII, and VIII, because none are required to make or use the nonpeptide luminophore coupled to a cyclic nucleotide of Invention IV. The kit of Invention VII is independent and distinct from the products of Inventions II, IV, and VIII because it is not required to make or use the kit of Invention VII. Finally, the lysis buffer of Invention VIII is independent and distinct from the products of Inventions II, IV, and VII, because none are required to make or use the lysis buffer composition of Invention VIII.

5. Inventions IV and each of V and VI are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process of using that product. The nonpeptide luminescently labeled tracer comprising a luminophore coupled to a cyclic nucleotide of Invention IV could be used to label GTPases and/or ATPases in immunocytochemistry.

6. Inventions II and each of I, III, V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of

operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of I, III, V, and VI are unrelated product and processes, wherein each is not required, one for another. For example, the claimed methods of Inventions I, III, V and VI do not recite the use or production of the nonpeptide luminescently labeled tracer comprising a luminophore coupled to a nonhydrolyzable guanosine triphosphate (GTPγ-S) of Invention II.

7. Inventions VII and each of I, III, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VII and each of I, III, V, and VI are unrelated product and processes, wherein each is not required, one for another. For example, the claimed methods of Inventions I, III, V, and VI do not recite the use or production of the kit of Invention VII.

8. Inventions VIII and each of I, III, V, and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions VIII and each of I, III, V, and VI are unrelated product and processes, wherein each is not required, one for another. For example, the claimed methods of Inventions I, III, V, and VI do not recite the use or production of the lysis buffer of Invention VIII.

9. This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Antibodies

b. GTP-binding proteins

c. G-protein-coupled receptors

d. Serpentine receptors and seven transmembrane-spanning domain receptors

10. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 3 and 12 are generic.

11. If applicant selects Invention I, one species from the specific binding partner group must be chosen to be fully responsive.

12. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

13. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

14. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

15. This application contains claims directed to the following patentably distinct species of the claimed invention:

e. Cyclic AMP (cAMP)

f. Cyclic GMP (cGMP)

g. Nonhydrolyzable GTP

16. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 4 and 9 are generic.

17. If applicant selects Invention I, one species from the nucleotide group must be chosen to be fully responsive.

18. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

19. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

20. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

21. This application contains claims directed to the following patentably distinct species of the claimed invention:

h. Enzyme

i. Extracellular receptor

j. Receptor

22. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-12, 15-16, and 22-34 are generic.

23. If applicant selects any one of Inventions I, III, V, VI, or VII one species from the activation target group must be chosen to be fully responsive.

24. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

25. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

26. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

27. This application contains claims directed to the following patentably distinct species of the claimed invention:

k. Adenylyl cyclase

l. Guanylyl cyclase

m. G-protein-coupled receptors

28. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 10 is generic.

29. If applicant selects Invention I, one species from the receptors/enzymes group must be chosen to be fully responsive.

30. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

31. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

32. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

33. This application contains claims directed to the following patentably distinct species of the claimed invention:

n. Cyclic AMP (cAMP)

o. Cyclic GMP (cGMP)

34. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claims 1-34 are generic.

35. If applicant selects any one of Inventions I, II, III, IV, V, VI, or VII one species from the cyclic nucleotide group must be chosen to be fully responsive.

36. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable

thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

37. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

38. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

39. This application contains claims directed to the following patentably distinct species of the claimed invention:

p. 1,2-diaminocyclohexyl

q. 1,4-diaminocyclohexyl

40. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 20 is generic.

41. If applicant selects Invention IV, one species from the rigid coupling group must be chosen to be fully responsive.

42. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

43. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

44. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

45. This application contains claims directed to the following patentably distinct species of the claimed invention:

r. Fluorescein-ITC-1,4-DACHsuccinimidyl cAMP

s. Fluorescein-ITC-1,2-DACHsuccinimidyl cAMP

t. Carboxyfluorescein-ITC-1,4-DACHsuccinimidyl cAMP

u. Carboxyfluorescein-ITC-1,2-DACHsuccinimidyl cAMP

v. Fluorescein-ITC-1,4-DACHsuccinimidyl cGMP

w. Fluorescein-ITC-1,2-DACHsuccinimidyl cGMP

x. Carboxyfluorescein-ITC-1,4-DACHsuccinimidyl cGMP

y. Carboxyfluorescein-ITC-1,2-DACHsuccinimidyl cGMP

46. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, Claim 21 is generic.

47. If applicant selects Invention IV, one species from the tracer group must be chosen to be fully responsive.

48. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

49. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

50. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

51. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

Summary

52. No claims are allowed.

Conclusion

53. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher Nichols, Ph.D. whose telephone number is 703-305-3955. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

54. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone number for the customer service center is 703-872-9305.

55. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Gary L. Kunz

CJN
August 23, 2002